

**AMENDMENT IN THE NATURE OF A SUBSTITUTE**  
**TO H.R. 3015**  
**OFFERED BY MR. WHITFIELD**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “\_\_\_\_\_ Act  
3 of 2004”.

**4 SEC. 2. CONTROLLED SUBSTANCE MONITORING PROGRAM.**

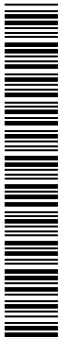
5 Part P of title III of the Public Health Service Act  
6 (42 U.S.C. 280g et seq.) is amended by adding after sec-  
7 tion 399N the following:

**8 “SEC. 399O. CONTROLLED SUBSTANCE MONITORING PRO-  
9 GRAM.**

10 “(a) FORMULA GRANTS.—

11 “(1) IN GENERAL.—Each fiscal year, the Sec-  
12 retary shall make a payment to each State with an  
13 application approved under this section for the pur-  
14 pose of establishing and implementing a controlled  
15 substance monitoring program under this section.

16 “(2) DETERMINATION OF AMOUNT.—In making  
17 payments under paragraph (1) for a fiscal year, the  
18 Secretary shall allocate to each State with an appli-  
19 cation approved under this section an amount which



1 bears the same ratio to the amount appropriated to  
2 carry out this section for that fiscal year as the  
3 number of pharmacies of the State bears to the  
4 number of pharmacies of all States with applications  
5 approved under this section (as determined by the  
6 Secretary), except that the Secretary may adjust the  
7 amount allocated to a State under this paragraph  
8 after taking into consideration the budget cost esti-  
9 mate for the State's controlled substance monitoring  
10 program.

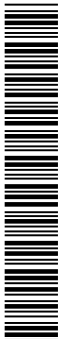
11 “(b) APPLICATION APPROVAL PROCESS.—

12 “(1) IN GENERAL.—To seek a grant under this  
13 section, a State shall submit an application at such  
14 time, in such manner, and containing such assur-  
15 ances and information as the Secretary may reason-  
16 ably require. Each such application shall include—

17 “(A) a budget cost estimate for the State's  
18 controlled substance monitoring program; and

19 “(B) assurances of compliance with the re-  
20 quirements of this section.

21 “(2) APPROVAL OR DISAPPROVAL.—Not later  
22 than 90 days after the submission by a State of an  
23 application under paragraph (1), the Secretary shall  
24 approve or disapprove the application. The Secretary  
25 shall approve the application if the State dem-



1       onstrates to the Secretary that the State will estab-  
2       lish and implement a controlled substance moni-  
3       toring program in accordance with this section.

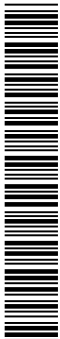
4               “(3) WITHDRAWAL OF AUTHORIZATION.—If a  
5       State fails to implement a controlled substance mon-  
6       itoring program in accordance with this section—

7               “(A) the Secretary shall give notice of the  
8       failure to the State; and

9               “(B) if the State fails to take corrective  
10       action within a reasonable period of time, the  
11       Secretary shall withdraw any approval of the  
12       State’s application under this section.

13               “(4) VOLUNTARY DISCONTINUANCE.—A fund-  
14       ing agreement for the receipt of a payment under  
15       this section is that the State involved will give a rea-  
16       sonable period of notice to the Secretary before ceas-  
17       ing to implement a controlled substance monitoring  
18       program under this section. The Secretary shall de-  
19       termine the period of notice that is reasonable for  
20       purposes of this paragraph.

21               “(5) RETURN OF FUNDS.—If the Secretary  
22       withdraws approval of a State’s application under  
23       this section, or the State chooses to cease to imple-  
24       ment a controlled substance monitoring program  
25       under this section, a funding agreement for the re-



1        ceipt of a payment under this section is that the  
2        State will return to the Secretary an amount which  
3        bears the same ratio to the overall payment as the  
4        remaining time period for expending the payment  
5        bears to the overall time period for expending the  
6        payment (as specified by the Secretary at the time  
7        of the payment).

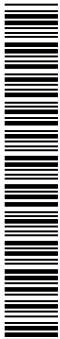
8        “(c) REPORTING REQUIREMENTS.—In implementing  
9        a controlled substance monitoring program under this sec-  
10       tion, a State shall comply with the following:

11                “(1) The State shall require dispensers to re-  
12        port to such State each dispensing in the State of  
13        a controlled substance to an ultimate user or re-  
14        search subject not later than 1 week after the date  
15        of such dispensing.

16                “(2) The State may exclude from the reporting  
17        requirement of this subsection—

18                        “(A) the direct application of a controlled  
19        substance to the body of an ultimate user or re-  
20        search subject;

21                        “(B) the dispensing of a controlled sub-  
22        stance in a quantity limited to an amount ade-  
23        quate to treat the ultimate user or research  
24        subject involved for 48 hours or less; or



1           “(C) the application or dispensing of a  
2           controlled substance in accordance with any  
3           other exclusion identified by the Secretary for  
4           purposes of this paragraph.

5           “(3) The information to be reported under this  
6           subsection with respect to the dispensing of a con-  
7           trolled substance shall include the following:

8           “(A) Drug Enforcement Administration  
9           Registration Number of the dispenser.

10          “(B) Drug Enforcement Administration  
11          Registration Number and name of the practi-  
12          tioner who prescribed the drug.

13          “(C) Name, address, and telephone num-  
14          ber of the ultimate user or research subject

15          “(D) Identification of the drug by a na-  
16          tional drug code number.

17          “(E) Quantity dispensed.

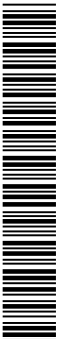
18          “(F) Estimated number of days for which  
19          such quantity should last.

20          “(G) Number of refills ordered.

21          “(H) Whether the drug was dispensed as  
22          a refill of a prescription or as a first-time re-  
23          quest.

24          “(I) Date of the dispensing.

25          “(J) Date of origin of the prescription.



1           “(4) The State shall specify an electronic for-  
2           mat for the reporting of information under this sub-  
3           section and may waive the requirement of such for-  
4           mat with respect to an individual dispenser.

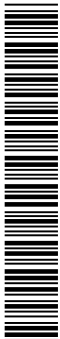
5           “(5) The State shall automatically share infor-  
6           mation reported under this subsection with another  
7           State with an application approved under this sec-  
8           tion if the information concerns—

9                   “(A) the dispensing of a controlled sub-  
10                  stance to an ultimate consumer or research sub-  
11                  ject who resides in such other State; or

12                   “(B) the dispensing of a controlled sub-  
13                  stance prescribed by a practitioner whose prin-  
14                  cipal place of business is located in such other  
15                  State.

16           “(6) The State shall notify the appropriate au-  
17           thorities responsible for drug diversion investigation  
18           if information in the database maintained by the  
19           State under subsection (d) indicates a potential un-  
20           lawful diversion or misuse of a controlled substance.

21           “(d) DATABASE.—In implementing a controlled sub-  
22           stance monitoring program under this section, a State  
23           shall comply with the following:



1           “(1) The State shall establish and maintain an  
2           electronic database containing the information re-  
3           ported to the State under subsection (c).

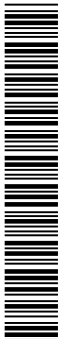
4           “(2) The database must be searchable by any  
5           field or combination of fields.

6           “(3) The State shall include reported informa-  
7           tion in the database at such time and in such man-  
8           ner as the Secretary determines appropriate, with  
9           appropriate safeguards for ensuring the accuracy  
10          and completeness of the database.

11          “(4) The State shall take appropriate security  
12          measures to protect the integrity of, and access to,  
13          the database.

14          “(e) PROVISION OF INFORMATION.—Subject to sub-  
15          section (f), in implementing a controlled substance moni-  
16          toring program under this section, a State may provide  
17          information from the database established under sub-  
18          section (d) and, in the case of a request under paragraph  
19          (2) or (3), compilations of such information, in response  
20          to a request by—

21                 “(1) a practitioner (or the agent thereof) who  
22                 certifies that the requested information is for the  
23                 purpose of providing medical or pharmaceutical  
24                 treatment or evaluating the need for such treatment  
25                 to a bona fide current patient;

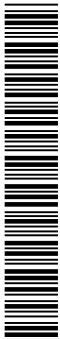


1           “(2) any local, State, or Federal law enforce-  
2           ment, narcotics control, licensure, disciplinary, or  
3           program authority, who certifies that the requested  
4           information is related to an individual investigation  
5           or proceeding involving the unlawful diversion or  
6           misuse of a schedule II, III, or IV substance, and  
7           such information will further the purpose of the in-  
8           vestigation or assist in the proceeding; or

9           “(3) any agent of the Department of Health  
10          and Human Services, a State medicaid program, a  
11          State health department, or the Drug Enforcement  
12          Administration who certifies that the requested in-  
13          formation is necessary for research to be conducted  
14          by such department, program, or administration, re-  
15          spectively, and the intended purpose of the research  
16          is related to a function committed to such depart-  
17          ment, program, or administration by law that is not  
18          investigative in nature.

19          “(f) LIMITATIONS.—In implementing a controlled  
20          substance monitoring program under this section, a  
21          State—

22               “(1) shall make reasonable efforts to limit the  
23               information provided pursuant to a valid request  
24               under subsection (e) to the minimum necessary to  
25               accomplish the intended purpose of the request; and





1           “(2) shall not provide any individually identifi-  
2           able information in response to a request under sub-  
3           section (e)(3).

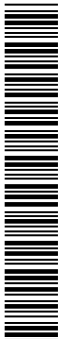
4           “(g) RULES OF CONSTRUCTION.—

5           “(1) FUNCTIONS OTHERWISE AUTHORIZED BY  
6           LAW.—Nothing in this section shall be construed to  
7           restrict the ability of any authority, including any  
8           local, State, or Federal law enforcement, narcotics  
9           control, licensure, disciplinary, or program authority,  
10          to perform functions otherwise authorized by law.

11          “(2) NO PREEMPTION.—Nothing in this section  
12          shall be construed as preempting any State law, ex-  
13          cept that no such law may relieve any person of a  
14          requirement otherwise applicable under this Act.

15          “(3) NO FEDERAL PRIVATE CAUSE OF AC-  
16          TION.—Nothing in this section shall be construed to  
17          create a Federal private cause of action.

18          “(h) RELATION TO HIPAA.—Except to the extent in-  
19          consistent with this section, the provision of information  
20          pursuant to subsection (c)(5), (c)(6), or (e) and the subse-  
21          quent transfer of such information are subject to any re-  
22          quirement that would otherwise apply under the regula-  
23          tions promulgated pursuant to section 264(c) of the  
24          Health Insurance Portability and Accountability Act of  
25          1996.



1       “(i) PREFERENCE.—The Secretary, in awarding any  
2 competitive grant that is related to drug abuse (as deter-  
3 mined by the Secretary) to a State, shall give preference  
4 to any State with an application approved under this sec-  
5 tion.

6       “(j) STUDY.—Not later than 1 year after the date  
7 of the enactment of this section, the Secretary shall—

8               “(1) complete a study on—

9                       “(A) the progress of States in establishing  
10 and implementing controlled substance moni-  
11 toring programs under this section; and

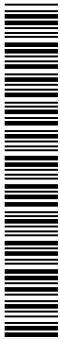
12                      “(B) the feasibility of implementing a real-  
13 time electronic controlled substance monitoring  
14 program, including the costs associated with es-  
15 tablishing such a program; and

16               “(2) submit a report to the Congress on the re-  
17 sults of the study.

18       “(k) ADVISORY COUNCIL.—

19               “(1) ESTABLISHMENT.—A State may establish  
20 an advisory council to assist in the establishment  
21 and implementation of a controlled substance moni-  
22 toring program under this section.

23               “(2) SENSE OF CONGRESS.—It is the sense of  
24 the Congress that, in establishing an advisory coun-  
25 cil under this subsection, a State should consult with



1 State boards of pharmacy, State boards of medicine,  
2 and other interested parties.

3 “(l) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘bona fide patient’ means an in-  
5 dividual who is a patient of the dispenser or practi-  
6 tioner involved.

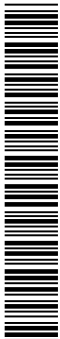
7 “(2) The term ‘controlled substance’ means a  
8 drug that is—

9 “(A) included in schedule II, III, or IV of  
10 section 202(c) of the Controlled Substance Act;  
11 or

12 “(B) identified by the State involved as a  
13 drug subject to the monitoring program of the  
14 State under this section.

15 “(3) The term ‘dispense’ means to deliver a  
16 controlled substance to an ultimate user or research  
17 subject by, or pursuant to the lawful order of, a  
18 practitioner, irrespective of whether the dispenser  
19 uses the Internet or other means to effect such deliv-  
20 ery.

21 “(4) The term ‘dispenser’ means a physician,  
22 pharmacist, or other individual who dispenses a con-  
23 trolled substance to an ultimate user or research  
24 subject.



1           “(5) The term ‘practitioner’ means a physician,  
2           dentist, veterinarian, scientific investigator, phar-  
3           macy, hospital, or other person licensed, registered,  
4           or otherwise permitted, by the United States or the  
5           jurisdiction in which he or she practices or does re-  
6           search, to distribute, dispense, conduct research with  
7           respect to, administer, or use in teaching or chemical  
8           analysis, a controlled substance in the course of pro-  
9           fessional practice or research.

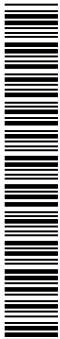
10           “(6) The term ‘State’ means each of the 50  
11           States and the District of Columbia.

12           “(7) The term ‘ultimate user’ means a person  
13           who has lawfully obtained, and who possesses, a con-  
14           trolled substance for his or her own use, for the use  
15           of a member of his or her household, or for the use  
16           of an animal owned by him or her or by a member  
17           of his or her household.

18           “(m) AUTHORIZATION OF APPROPRIATIONS.—To  
19           carry out this section, there are authorized to be  
20           appropriated—

21           “(1) \$25,000,000 for each of fiscal years 2006  
22           and 2007; and

23           “(2) \$15,000,000 for each of fiscal years 2008,  
24           2009, and 2010.”.



Amend the title so as to read: “A bill to provide for the establishment of a controlled substance monitoring program in each State.”.

